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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,190	02/20/2001	Klaus-Dieter Vorlop	64251-010	9277

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EXAMINER	
REDDICK, MARIE L	

ART UNIT	PAPER NUMBER
1713	

DATE MAILED: 08/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/720,190	VORLOP ET AL.
	Examiner	Art Unit
	Judy M. Reddick	1713

-- The MAILING DATE of this communication appears on the cov r sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *25-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-30* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Newly submitted claims 25-30 are directed to an invention that lacks unity with the invention originally claimed for the following reasons: The originally presented invention(claims 1-24, submitted with the Demand)) is drawn to a process for producing a bio-catalyst vs. the newly presented invention(claims 25-30) which is drawn to a) a mechanically high stable bio-catalyst of polyvinyl alcohol and b) a process for producing bio-catalyst, transformed product(s), the two inventions being separate and distinct as per the inventions do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the inventions lack the same or corresponding special technical features since the processes of Charmot et al(U.S. 4,737,533) and Venkatraman et al render the claims of the instant invention unpatentable under 35 USC 103(a) and to this end, the Group I invention does not define a contribution over the prior art. See Rule 13.2 which reads as follows: Circumstances in Which the Requirement of Unity of Invention Is to Be Considered Fulfilled- Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. .

2. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 25-30 have been withdrawn from consideration as being directed to a nonelected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections – 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> *The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*

4. Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) The recited "an aqueous polyvinyl alcohol solution with a degree of hydrolysis of at least 98 mol%" per claim 1 a) constitutes indefinite subject matter as per it not clear, from the language as claimed, if the "degree of hydrolysis" is intended to qualify the "aqueous solution" or the "polyvinyl alcohol" component. It is suggested that applicant adopt the following language: "a) utilizing an aqueous polyvinyl alcohol solution wherein the polyvinyl alcohol has a degree of hydrolysis of at least 98 mol%".

B) The recited "wherein the polyvinyl alcohol solution has a concentration of 4 – 30 wt. %" per claim 2 and the recited "wherein the polyvinyl alcohol solution has a concentration of 6 – 16 wt.%" per claim 3 constitute indefinite subject matter as per it not being clear if the "solution" or the "polyvinyl alcohol" is intended to have the recited concentration. Further, it is not clear as to what the concentration is based on, i.e., "polyvinyl alcohol" + "additive" + "biologically active material" or else.

C) The recited "wherein the additive has a concentration in a range of 4 – 20 wt.%" per claim 7 and "wherein the additive has a concentration in the range of 6 – 10 wt.% per claim 8 constitutes indefinite subject matter as per the entity that said recited ranges are being based on is not readily ascertainable, i.e., "aqueous polyvinyl alcohol solution" + additive + "biologically active material" or else.

D) The recited "the gel substance is formed with a diameter <u>that is at least double a height of the gel substance"</u> per claim 13 constitutes indefinite subject matter as per a) the non-express establishment of proper antecedent basis; b) said phrase engenders an ambiguity.

E) The recited "the gel substance" per claims 14 and 15 engenders the non-express establishment of proper antecedent basis.

F) The recited "further including the step of adding a biologically active material" per claim 20 constitutes indefinite subject matter as per it not being readily ascertainable as to how said "biologically active material" further limits the antecedently recited "biologically active material".

G) In claim 24 @ line 1 and line 3, it is suggested that applicant insert of between "dehydrating" and "the" and "a between "created" and "drop" per lines 1 and 3, respectively so as to maintain claim language clarity.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> *(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.*

6. The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. *Determining the scope and contents of the prior art.*
2. *Ascertaining the differences between the prior art and the claims at issue.*
3. *Resolving the level of ordinary skill in the pertinent art.*
4. *Considering objective evidence present in the application indicating obviousness or nonobviousness.*

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1- 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charmot et al(U.S. 4,737,533).

Charmot et al disclose dry material which can be hydrated into an aqueous gel comprising (1) a matrix comprising a macromolecular substance A which includes proteins, capable of forming a porous aqueous gel when it is in the presence of water, (2) a water-soluble linear polymer B which includes polyethylene glycols governed by a weight average molecular weight of about 1,000 and polyvinyl alcohol, (3) a plasticizer for the macromolecular substance A which includes polyethylene glycols having a weight average molecular weight of less than 400 and, (4) dispersed in the matrix, particles of a polymer C obtained from at least one water-immiscible monomer. Charmot et al further teach that the antecedently recited material can be obtained by mixing an aqueous solution of macromolecular substance A with the polymer B, the plasticizer and a latex of polymer C, followed by cooling, shaping and drying of the aqueous gel obtained. The dry material can be used in biological applications after rehydration. Charmot et al, @ col. 4, lines 39 – 52, teach that polymer C may be "sensitized" which means that biologically active substances such

as antibodies, antigens, drugs and enzymes are immobilized on the particles of polymer C and that the particles of polymer C included in the matrix are polymer particles which can be magnetized. More specifically, Charmot et al @ col. 5, lines 2-40 teach that the dry material which can be hydrated is obtained via (1) mixing (a) an aqueous solution of a macromolecular substance A capable of forming, after preferably cooling to a temperature of 30 to 80 degree C, a porous aqueous gel when the substance A is in the presence of water, at a preferred concentration of the substance A effective for forming the gel at a temperature of 30 to 80 degrees C, (b) a water-soluble linear polymer B, (c) a plasticizer for the macromolecular substance A, and (d) a latex of a polymer C and wherein mixing occurs at a temperature greater than the gelling temperature of the aqueous solution of the macromolecular substance A; 2) cooling the resultant mixture to a temperature less than the gelling temperature of the aqueous solution of the macromolecular substance A and shaping the aqueous gel obtained during the cooling wherein, the shaping process consists of pouring the mixture obtained in the mixing stage onto a support consisting of a transparent thermoplastic plate which is placed on a horizontal glass plate, allowing the mixture to cool to form an aqueous gel which adheres to the plate, and covering the aqueous gel film with a regenerated cellulose-based sheet soaked in an aqueous solution of glycerol wherein the sheet of regenerated cellulose is folded back under the glass plate and (3) drying the shaped aqueous gel at a temperature less than the gelling temperature of the aqueous solution of the macromolecular substance A. Charmot et al @ col. 6, lines 46-66 also teach that a gel in the form of a film may be obtained by pouring the mixture on a glass plate and allowing it to cool to convert the liquid film deposited into an aqueous gel film. The aqueous gel film may then be demolded and dried. Lastly Charmot et al @ col. 7, lines 3-22 teach that the product is particularly valuable for its uses in biological applications, the porous nature of the gel of the macromolecular substance A enables proteins to reach the particles of polymer C and to become bound thereto by absorption or covalency and the dry material which can be hydrated into an aqueous gel containing dispersed polymer particles and has the advantage of combining the positive properties of the matrix, i.e., of being (1) capable of being hydrated at the desired time into a porous aqueous gel in such forms as films, plates, sticks, pellets and beads which can be easily handled, (2) compatible even with aqueous media with high concentrations of electrolytes, and (3) permeable to high molecular weight proteins, with the positive properties of the polymer particles derived from a water-immiscible monomer, viz. having a high and controlled specific surface area and a wide range of available chemical groups on the surface. See, e.g., the Abstract, cols. 1, 2, 4-7, the Runs and claims of Charmot et al.

The disclosure of Charmot et al differs basically from the claimed invention as per the non-specificity relative to the polyvinyl alcohol component, as claimed. However, the "polyvinyl alcohol" component per Charmot et al is generic to the claimed "polyvinyl alcohol" component and necessarily implies that any "polyvinyl alcohol", including the claimed "polyvinyl alcohol" would have been operable within the scope of patentees invention and with a reasonable expectation of success. Moreover, the use of any commercially available polyvinyl alcohol component in lieu of the polyvinyl alcohol component of Charmot et al would have been obvious to the skilled artisan and with a reasonable expectation of success, criticality for such, commensurate in scope with the claims, not have been demonstrated on this record. Moreover, the content of water removal although generic, such is a necessary implication that any water content removal, including the claimed content of water removal, would have been obvious to the skilled artisan and with a reasonable expectation of success.

While Charmot et al do not expressly recognize the generation of a "bio-catalyst" from the disclosed process, motivation in the prior art does not have to be the same as that for the claimed invention as provided for under the guise of In re Kemps, 30 USPQ2d 1309(Fed. Cir. 1996). Moreover, the formation of the here recited bio-catalyst would merely follow as a necessary incident to the selection of the recited steps based solely on the motivation or suggestion provided in Charmot et al. It would be reasonably expected that a phase separation of the polyvinyl alcohol solution of Charmot et al, as modified, would occur since the process parameters and components of Charmot et al, as modified, are essentially the same as the claimed process parameters and components and in the absence of the USPTO to have at its disposal the tools and facilities deemed necessary to make physical determinations of this sort. As to the remaining process parameters of the dependent claims, the limitations are either taught by Charmot et al, suggested by Charmot et al or would have been obvious to the skilled artisan and with a reasonable expectation of success.

Claim Rejections - 35 USC § 103

9. *Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Venkatraman et al(U.S. 6,039,977).*

Venkatraman et al teach pharmaceutical formulations. More particularly, Venkatraman et al teach pharmaceutical hydrogel formulations containing polyvinyl alcohol, water, a therapeutically effective amount of a drug and other additives which are useful in a variety of contexts, including electrotransport drug delivery, methods for

making the formulations, electrotransport drug delivery systems containing the hydrogel formulations as drug reservoirs and methods for substantially eliminating syneresis in a polyvinyl alcohol hydrogel system, said method involving selecting a degree of hydrolysis and corresponding percent by weight of polyvinyl alcohol in the gel that is effective in forming a hydrogel which is stable to syneresis. In making the formulations, Venkatraman et al teach that the method entails dissolving a predetermined amount of polyvinyl alcohol in an aqueous liquid, combining the polymer solution with a therapeutically effective amount of drug and other additives, and gelling the solution by a freeze-thaw process in which thawing is conducted for a time period of 5 hours or less. The resultant hydrogel is mechanically strong and stable to syneresis. The formulation may be used to form a drug reservoir for passive transdermal drug delivery or for electrotransport drug delivery. Venkatraman et al further teach that alternatively, the formulation may be combined with a pharmaceutically acceptable carrier suitable for other modes of drug administration wherein, suitable carrier materials include, inter alia, polyethylene glycol(sufficient to meet the additive b) per the claimed invention). More specifically, Venkatraman et al teach that an alternative method for incorporating the drug and other desired additives into the hydrogel involves forming the gel in the absence of drug, removing the water(dehydrating), and hydrating the gel with an aqueous drug solution containing the other desired additives. Venkatraman et al teach that this method is particularly useful for drugs and/or formulation additives that are heat-sensitive. Most specifically, Venkatraman et al @ col. 9, lines 1+ teach that the invention is also useful in conjunction with the electrotransport delivery of proteins, peptides and fragments thereof(sufficient to meet the biologically active material c) per the claimed invention), whether naturally occurring, chemically synthesized or recombinantly produced. See, e.g., the Abstract, col. 1, lines 1-15. col. 3, lines 29-67, col. 4, lines 1-67, col. 5, lines 6-65 and cols. 6-9 of Venkatraman et al. In terms of the polyvinyl alcohol component of the hydrogel, Venkatraman et al @ least at col. 5, lines 56+ teach that the percent by weight of polyvinyl alcohol in the hydrogel, Y, is selected to correspond to the degree of hydrolysis of the polymer, Dh. When the Dh is in the range of approximately 95% to 99.9%, Y is in the range of approximately 10 wt. % to 30 wt. % and preferably, in the range of approximately 96% to 99% and Y is in the range of approximately 12 wt. % to 25 wt. %, sufficient to meet the limitations per the instantly claimed invention.

The disclosure of Venkatraman et al differs basically from the claimed invention, with the understanding that the claimed steps are not required to be performed in a sequential fashion, in that the content of water removal is expressly disclosed and therefore generic to the claimed water removal content and necessarily implies that any

amount of water removal, including the claimed content of water removal, would have been operable within the scope of patentee's invention and with a reasonable expectation of success, absent a clear showing of criticality for such clearly commensurate in scope with the claimed invention. As to the remaining process parameters per the dependent claims, the disclosure of Venkatraman et al is generic to these parameters which necessarily implies that any process parameters, including the claimed process parameters, would have been operable within the scope of patentee's invention and with a reasonable expectation of success. Venkatraman et al is provided by virtue of 102(e).

While Venkatraman et al do not expressly recognize the generation of a "bio-catalyst" from the disclosed process, motivation in the prior art does not have to be the same as that for the claimed invention as provided for under the guise of In re Kemps, 30 USPQ2d 1309(Fed. Cir. 1996). Moreover, the formation of the here recited bio-catalyst would merely follow as a necessary incident to the selection of the recited steps based solely on the motivation or suggestion provided in Venkatraman et al . It would be reasonably expected that a phase separation of the polyvinyl alcohol solution of Venkatraman et al , as modified, would occur since the process parameters and components of Venkatraman et al , as modified, are essentially the same as the claimed process parameters and components and in the absence of the USPTO to have at its disposal the tools and facilities deemed necessary to make physical determinations of this sort.

Response to Arguments

12. Applicant's arguments coupled with the claim amendments, see paper no. 9, filed 12/11/02, with respect to the rejection(s)of claim(s) 1-3 under 35 USC 103(a) as obvious over DE 4,327,923 in combination with Allen et al(U.S. 4,746,551) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.

Conclusion

13. The additional prior art listed on the attached PTOL FORM 892 is cited as of being illustrative of the general state of the art..

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Judy M. Reddick whose telephone number is (703)308-4346. The examiner can normally be reached on Monday-Friday, 6:30 a.m.-3:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on (703)308-2450. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)305-8183.

Judy M. Reddick
Primary Examiner
Art Unit 1713

JMR
8/14/03